PATENT COOPERATION TREATY

PCT 10/591364

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 10457-058PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2005/008896	International filing date *(day/month/year)* 16 March 2005 (16.03.2005)	Priority date *(day/month/year)* 16 March 2004 (16.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 September 2006 (19.09.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Philippe Becamel e-mail: pt12@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
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390 N. ORANGE AVENUE, STE. 2500
ORLANDO, FL 32801

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	23 JUN 2005
Applicant's or agent's file reference 10457-058PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/08896	16 March 2005 (16.03.2005)	16 March 2004 (16.03.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 33/53 and US Cl.: 422/55,101; 436/510,518,525,528,530,541,810,814,818; 435/7.92,7.95,805,806,810,970

Applicant

UNIVERSITY OF FLORIDA RESEARCH FOUNDATION

1. This opinion contains indications relating to the following items:

- [x] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [x] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Gailene R. Gabel Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/08896

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/08896

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 9-12	YES
	Claims 1-8	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-12	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1 and 4-7 lack novelty under PCT Article 33(2) as being anticipated by Lowne (US Patent 4,552,458).

Lowne discloses an apparatus (compact reflectometer) for analyzing the amount of analyte in a body fluid sample comprising a housing support for receiving a disposable diagnostic reagent unit (planar test element), a light source, a light sensor (detector) for measuring light from the source and reflected from the unit, wherein an optical characteristic representative of the presence or concentration of analyte is manifested by a change in electrical signal. The apparatus further comprises a microprocessor (microcomputer and signal processing circuit) and a display responsive to the signal and which also provides a visual readout (see Abstract, Figure 1, Figure 6, and columns 5-7).

Claims 2 and 3 lack novelty under PCT Article 33(2) as being anticipated by Knapen et al. (Haemostasis 30(6): 290-297 (Nov-Dec 2000)) (Abstract).

Knapen et al. teach determining the proper dosage of oral anticoagulant by measuring the vitamin K nutritional status of a patient and modulating the dosage based on the result obtained. According to Knapen, the degree of carboxylation of osteocalcin (bone G1A proteins) is differentially affected by oral anticoagulant treatment. (See Abstract)

Claim 8 lacks novelty under PCT Article 33(2) as being anticipated by Davis et al. (US Patent 6,352,862).

Davis et al. disclose a diagnostic reagent unit for analyzing a liquid sample for the presence of a marker comprising a liquid sample application member, a liquid sample receiver having mobilizable labeled antibody for binding the marker, and dry porous carrier strip including a detection zone having an unlabeled immobilized capture antibody for binding the marker.

Claims 9-12 lack an inventive step under PCT Article 33(3) as being obvious over Davis et al. (US Patent 6,352,862) in view of Knapen et al. (Haemostasis 30(6): 290-297 (Nov-Dec 2000)) (Abstract) or Pietschmann et al. (Journal of Clinical Endocrinology and Metabolism 66 (5): 1071-1074 (May 1988)) (Abstract).

Davis et al. has been discussed supra.

Davis et al. differ from the claimed invention in failing to disclose that the marker is carboxylated osteocalcin and the labeled antibody is anti-carboxylated osteocalcin antibody.

Knapen et al. has been discussed supra.

Pietschmann et al. teach measuring osteocalcin using radioimmunoassay (labeled antibodies to osteocalcin) in subjects receiving phenprocoumon anticoagulant. According to Pietschmann, carboxylation of osteocalcin (bone G1A proteins) is impaired in subjects receiving the anticoagulant treatment. (See Abstract)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Knapen and Pietschmann into the reagent test strip as taught by Davis because test strips are conventional and well known in the art for their recognized advantages of convenience and economy

Claims 1-12 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability in the field of hematological diagnostic

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In case the space in any of the preceding boxes is not sufficient.

medicine because the subject matter claimed can be made or used in industry.